

NDA 18-731/S-039
NDA 18-731/S-045
NDA 18-731/S-020, S-033, S-034 (FPL)

Bristol-Myers Squibb Company
Attention: Michael Eison, Ph.D.
Director, Regulatory Science
5 Research Parkway
Wallingford, CT 06492

Dear Dr. Eison:

Please refer to your supplemental new drug applications dated August 20, 1998(S-039) and November 8, 2000 (S-045) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BuSpar® (buspirone HCl) Tablets.

We also refer to the FPL submission dated June 17, 1998 for approved supplements: S-020, S-033 and S-034.

Further reference is made to the May 1, 2001, teleconference between Dr. Mike Eison of Bristol-Myers Squibb, and Ms. Anna Marie Homonnay, Regulatory Health Project Manager of FDA during which an additional labeling change was agreed upon.

We acknowledge receipt of your amendment dated June 27, 2000 to (S-039).

These supplemental new drug applications provide for the following:

1. S-039 provides for geriatric use labeling language in the PRECAUTIONS section.
2. S-045 provides for changes to the DESCRIPTION (indicating that the 5 mg and 10 mg tablets are scored), PRECAUTIONS (addressing interactions with food, grapefruit juice, diltiazem, verapamil, erythromycin, itraconazole, nefazadone, rifampin, and other inhibitors and inducers of CYP3A4), and DOSAGE AND ADMINISTRATION (cross-referencing the dosing recommendations in 'Drug Interactions') sections of the labeling.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental applications are approved effective on the date of this letter.

Please note that the FPL submission dated June 17, 1998, for S-020, S-033 and S-034 has been superceded by S-045.

The final printed labeling (FPL) must be identical to the enclosed draft labeling with the agreed upon changes (package insert submitted November 8, 2000).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-731/S-045." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you should have any questions, please call Ms. Anna Marie Homonnay, R.Ph., Regulatory Project Manager, at (301) 594-5535.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research